

Biotechnology is the most scrutinized new technology in history

The regulatory process in the United States

Origin and development:

National Institutes of Health, Guidelines, 1976, 1983, and subsequent revisions

White House Office of Science and Technology Policy (OSTP):
1984: Coordinated Framework of legislative authorization to agencies

National Academy of Sciences, Studies and Recommendations
1987, 1989, 1999, 2000, and 2002

Overview of the coordinated framework for regulatory review of biotechnology crops in the USA		
Example Trait/Organism	Review Conducted by:	Reviewed for:
Viral resistance in food crop	USDA EPA FDA	Safe to grow Safe for the environment Safe to eat
Insect resistance in food crop	EPA USDA FDA	Safe for the environment Safe to grow Safe to eat
Herbicide tolerance in food crop	USDA EPA FDA	Safe to grow New use of the herbicide Safe to eat
Herbicide tolerance in ornamental crop	USDA EPA	Safe to grow New use of companion herbicide
Modified oil content in food crop	USDA FDA	Safe to grow Safe to eat
Modified ornamental flower color	USDA	Safe to grow
Pharmaceutical product in any crop	USDA FDA	Safe to grow Safe for medicinal use
Modified soil bacteria that degrade pollutants	EPA	Safe for the environment

USDA: U.S. Dept. Agriculture (APHIS, Animal and Plant Health Inspection Service),
www.usda.gov, www.aphis.usda.gov

EPA: Environmental Protection Agency, www.epa.gov

FDA: Food and Drug Agency, www.cfasan.fda.gov